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EP 0 594 349 B1

(12)

## **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent: 15.07.1998 Bulletin 1998/29 (51) int. Cl.<sup>6</sup>: **A61M 5/50**, A61M 5/315, A61M 5/24

(11)

(21) Application number: 93308160.6

(22) Date of filing: 13.10.1993

# (54) Syringe with device to prevent refilling

Injektionsspritze mit Vorrichtung zur Verhinderung eines erneuten Nachfüllens Seringue avec dispositif pour empêcher un nouveau remplissage

(84) Designated Contracting States:
AT CH DE DK ES FR GB GR IT LI NL SE

(30) Priority: 20.10.1992 US 963815

(43) Date of publication of application: 27.04.1994 Bulletin 1994/17

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### Description

This invention is in the field of devices for injecting precisely metered doses of pharmaceutical agents. The invention particularly relates to a hypodermic syringe having the same general appearance as a pen or mechanical pencil which is specifically adapted to provide for multiple measured doses of agents such as insulin or human growth hormone.

Diabetics and others frequently find themselves in situations where the assistance of a health professional is unavailable to administer a subcutaneous or intramuscular injection of measured amount of a liquid agent. In such situations such persons need to have a low-cost syringe which does not require the assistance of a health professional to achieve the desired measure of accuracy. It is often the case that such persons require more than one dose per day, each dose being of a somewhat different volume. Dispensers of this general type are known which are the general appearance of a pen or mechanical pencil. The dispenser is typically large enough to hold several such doses, yet it is small enough to fit conveniently in one's pocket or purse. Examples of such devices are to be found in U.S. Patents Nos. 4,973,318; 4,413,760; 4,498,904; 3,613,952; 4,475,905; 4,883,472; and 4,592,745. Additional examples are show in PCT International Publications WO 87/02895; WO 88/07874; WO 82/02662; PCT CH 86/00151; PCT DK 88/0064.

In devices of this class, a container of the liquid is generally provided having a closed first end adapted to be penetrated by a needle assembly so as to permit the liquid in the container to pass out the injection. The second end of the container is generally closed by a piston. To prevent tampering or reuse of the liquid container, the piston is generally designed such that a pushing force can be applied to the piston to reduce the liquid-holding volume of the container, but no feature is presented which would be suitable for pulling on the piston so as to enlarge the liquid-holding volume of the container.

An elongated member in the nature of a plunger rod is received within the housing for exerting a force on the piston closing the second end of the container. A means is provided for measuring the distance which the plunger rod travels to determine the decrease in volume of the liquid container which causes the dispensing of the liquid within the container. It has generally been recognized that the dispenser should have some feature which would allow the rod to only travel in a single direction toward the piston thereby preventing any action on the part of the rod which might permit an enlargement of the volume of the liquid container. A safety cover is generally provided over a needle assembly attached to the closed end of the container.

EP-A-416975 discloses a multi-dose syringe having a nut on a threaded piston in the barrel, comprising a pawl means on the nut which cooperates at all times with a ratchet means within the barrel.

While the prior art pen-style syringes have met with some success, certain shortcomings have also been observed. In some prior art pens it is difficult to be sure that after a dose has been administered there is not a back-up which unintentionally alters the length of the piston stroke for the next dose.

The present invention provides a syringe in accordance with claim 1 having an anti-backup device which prevents the nut from moving up the threaded piston at the end of the dose by rotating in the opposite direction of that in which the nut moves up the position to set the new dose. In this way, it is assured that movement of the nut up the threaded piston is due to rotating the dose knob in the proper direction.

The invention provides a syringe with an improved device for preventing the backing up of a nut on a threaded piston rod in the barrel of a hypodermic syringe at the end of a dose comprising a pawl means on the nut which cooperates with a rachet means within the barrel and a means on the nut which cooperates with a means in the barrel for forcing the pawl means into the rachet means at the end of the dose to prevent rotation of the nut in the opposite direction to the dose setting direction.

This invention preferably encompasses a syringe with an improved device for preventing the backing up of a nut on a threaded piston rod in the barrel of a hypodermic syringe at the end of a dose comprising a pawl on the end of the nut which cooperates with slots on the inside of the syringe barrel of the hypodermic syringe to permit the nut to move up the threaded piston rod to set the dose and a first surface at the end of the nut which cooperates with a second surface in the barrel at the end of the dose to drive the pawl into a slot in the barrel and prevent rotation of the nut in the direction opposite to the dose setting direction.

Preferably, the pawl is mounted on a flexible arm integrally molded at the end of the nut and the first surface at the end of the nut is an inclined plane and the second surface in the barrel is an inclined plane mating with the first inclined plane wherein the mating of the inclined planes at the end of the dose prevent the flexible pawl arm from moving inward and maintains the pawl in a slot in the barrel and thereby prevents rotation in the wrong direction.

Figure 1 is a top view of the operative syringe.

Figure 2 is a sectional view of the anti-backup mechanism.

Figure 3 is a partial sectional view plane  $\underline{\mathbf{a}}$  of Figure 2.

Figure 4 is a perspective cut-away view of the anti-backup mechanism.

Figure 5 shows the disassembled parts in mix sectional and top views.

The syringe assembly 1 is shown in Figure 1. The

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syringe assembly 1 includes a needle assembly 2 which is coupled at the distal end of a syringe 3 which holds within it a container 4 containing the liquid to be administered. A threaded piston rod 5 contacts plunger 6 such that the piston 5 moves plunger 6 and downward movement forces liquid out of the needle. Overcap 7 is slidably received by the proximal end of the syringe housing 3. A pocket clip 8 is integrally molded as a part of overcap 7. A dose knob 15 fits into an opening 11 at the proximal end of the overcap 7. Rotating dose knob 15 cause an internal nut coupled to the dose knob to rideup piston 5 and effectively elongates a piston so that the dose knob occupies position 15b which corresponds to a precisely metered dose which can be observed on a scale through window 12. Pushing the dose knob from position 15b to position 15a causes a precisely metered amount of liquid to be ejected through the needle.

The precise description of devices of Figure 1 as generally explained above is set out in published European Application No. 496,141 (published July 29, 1992).

Now referring to Figures 2-5 which describe the details of the preferred embodiment of this invention.

Figure 2 illustrates the setting of the dose by turning the dose knob  $\underline{15}$  in a clockwise direction. This causes the dose knob to move from position 15(a) to 15(b) and the nut  $\underline{10}$  to move on the threaded piston rod  $\underline{5}$  in the direction of the dose knob to set the dose. During this operation, the threaded piston rod is held in place by push nut  $\underline{20}$  and the prong  $\underline{21}$  of the push nut which keeps the threaded piston rod  $\underline{5}$  from turning as well as moving toward the dose knob. Also, when the dose knob is turned in the clockwise direction, the pawl  $\underline{25}$  on the nut  $\underline{10}$  overcomes the slot  $\underline{26}$  in the barrel  $\underline{27}$ .

When the dose knob 15 is pushed to deliver the dose, the beveled end of the nut 28 assumes position 30 such that the end of the nut engages the beveled surface of circular inclined plane 29 on the inside of the barrel 27 at the end of the dose position. An attempt to rotate the dose knob 15 in a counterclockwise position results in pressure of nut surface 28 against the beveled surface of circular inclined plane 29. The pawl 25 on the nut 10 now moves up the circular inclined plane 29 and into the barrel slot 26 to further restrict the backup of the nut 10. The flange 21 on the push nut 20 prevents the threaded piston rod from moving in the direction of the dose knob. Thus, the mating of incline planes at the end of the nut and in the barrel prevents the flexible arm 32 on which the pawl is mounted from flexing inward and drives the pawl into the slot when an attempt to turn the nut counterclockwise is made.

Figure 3 shows a perspective partial sectional view of the anti-backup improvement. This view shows the threaded piston rod 5 with grooves 35 and the flange 21 of push nut 20 which prevents the threaded piston rod from turning or moving toward the dose knob. Figure 3 also shows the mating of incline plane surfaces 28 and 29 on the nut and inside the barrel respectively. Also shown is pawl 25 and slots 26 on the inner surface of

the barrel <u>27</u>. The relationship of the nut <u>10</u> to the threaded piston rod is also shown.

Figure 4 shows a partial cross-sectional view of Figure 2 through plane 4-4. Figure 4 illustrates how pawl 25 is mounted on a flexible arm 32 so that it springs in and out of slots 26 barrel 27 when the nut is rotated to set the dose. The arrow shows the direction of rotation to move the nut up the threaded piston to set the dose. At the end of the dose when dose knob 15 is pushed as far as it will go toward the overcap to deliver the dose the pawl 25 is driven into the slot 26 to prevent the nut from backing up by the interacting of incline planes 28 and 29.

Figure 5 shows disassembled components: threaded piston rod  $\underline{5}$ , nut  $\underline{10}$ , slotted barrel  $\underline{27}$ , push nut  $\underline{20}$ , dose knob  $\underline{15}$ , and cover  $\underline{30}$ . The cylinder  $\underline{16}$  of the dose knob tightly fits into the opening  $\underline{16}$  of the nut  $\underline{10}$  to effectively become one piece such that when the dose knob is turned, the nut turns. The nut  $\underline{10}$  is threaded on the threaded piston rod  $\underline{5}$ . The pawl section of the nut  $\underline{10}$  is inserted into the slotted barrel  $\underline{18}$ . The end of the threaded piston rod is set in the push nut  $\underline{20}$  which is located at position  $\underline{19}$  in the barrel. Overcap  $\underline{7}$  has opening  $\underline{11}$  for receiving cylinder  $\underline{16}$ .

Push nut <u>20</u> is made of a metal such as copper, or stainless steel. The other parts are molded plastic parts such as the dose knob, threaded piston rod, nut, slotted barrel, and overcap.

Those skilled in this art will recognize shapes and sizes, and position of surfaces on the nut and in the barrel which will force the pawl into a slot at the end of a dose. Similarly, those skilled in this art will recognize various pawl and rachet combinations and positioning to accomplish the purposes of the invention.

The embodiments of the invention described above are intended to illustrate the invention and not to limit it in scope.

### Claims

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1. A syringe having a barrel suitable for holding a container containing liquid to be administered comprising a piston rod (5) having threads located within the barrel, a dose knob (15) located at the proximal end of such syringe and an internal nut (10) coupled to the dose knob and threadably attached to the piston rod used to set the dose of liquid to be administered, and a pawl means (25) on the nut (10) which cooperates with a ratchet means (26) within the barrel characterized in that movement of the nut toward the distal end of the piston rod at the end of liquid dose administration is prevented by said pawl means (25) on the nut in cooperation with said ratchet means (26) within the barrel and wherein there is a means on the nut (28) which cooperates with a means on the barrel (29) for forcing the pawl means into the ratchet means only at the end of the dose so as to prevent rotation of the 15

nut in the direction opposite from that direction in which the nut rotates when setting the dose of liquid to be administered.

- 2. A syringe according to Claim 1 further characterized in that the pawl means on the nut is a pawl on the end of the nut which cooperates with slots on the inside of the syringe barrel to permit the nut to move up the threaded piston rod toward the proximal end of the syringe when setting the dose of liquid to be administered and that the means on the nut which cooperates with the means on the barrel are a first surface at the end of the nut and a second surface on the barrel, respectively.
- 3. A syringe according to Claim 2 further characterized in that the pawl is mounted on a flexible arm (32), the first surface at the end of the nut is an inclined plane and the second surface on the barrel is an inclined plan mating with the first inclined plan wherein the mating of the inclined planes prevents the flexible pawl arm from moving inward and maintains the pawl in a slot (26) in the barrel.

### Patentansprüche

- 1. Spritze mit einem Zylinder, der zum Halten eines Behälters geeignet ist, der zu verabreichende Flüssigkeit aufnimmt, enthaltend einen Kolbenstab (5) mit Gewinde, der sich im Zylinder befindet, einen Dosierknopf (15), der sich am äußeren Ende dieser Spritze befindet, und eine innere Schraubhülse (10), die an den Dosierknopf gekoppelt und schraubbar am Kolbenstab angebracht ist und verwendet wird, die zu verabreichende Flüssigkeitsdoeinzustellen, sowie eine Sperrklinkeneinrichtung (25) an der Schraubhülse (10), die mit einer Rasteneinrichtung (26) innerhalb des Zylinders zusammenwirkt, dadurch gekennzeichnet, daß die Bewegung der Schraubhülse zum vorderen Ende des Kolbenstabes am Ende der Verabreichung der Flüssigkeitsdosis durch die Sperrklinkeneinrichtung (25) an der Schraubhülse in Zusammenwirken mit der Rasteinrichtung (26) innerhalb des Zylinders verhindert wird, und bei der sich eine Einrichtung (28) an der Mutter Schraubhülse befindet, die mit einer Einrichtung (29) am Zylinder zusammenwirkt, um die Sperrklinkeneinrichtung in die Rasteneinrichtung nur am Ende der Dosis zu drücken, um so eine Drehung der Schraubhülse entgegengesetzt zu jener Richtung zu verhindern, in der sich die Schraubhülse dreht, wenn die zu verabreichende Flüssigkeitsdosis eingestellt wird.
- Spritze nach Anspruch 1, weiterhin dadurch gekennzeichnet, daß die Sperrklinkeneinrichtung an der Schraubhülse eine Sperrklinke am Ende der

Schraubhülse ist, die mit Schlitzen an der Innenseite des Spritzenzylinders zusammenwirkt, um zu ermöglichen, daß sich die Schraubhülse auf dem Gewindekolbenstab nach oben zum hinteren Ende der Spritze bewegt, wenn die Dosis der zu verabreichenden Flüssigkeit eingestellt wird, und dadurch daß die Einrichtung an der Schraubhülse, die mit der Einrichtung am Zylinder zusammenwirkt, aus einer ersten Oberfläche am Ende der Schraubhülse und einer zweiten Oberfläche am Zylinder besteht.

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3. Spritze nach Anspruch 2, weiterhin dadurch gekennzeichnet, daß die Sperrklinke an einem flexiblen Arm (32) befestigt ist und die erste Oberfläche am Ende der Schraubhülse eine geneigte Ebene und die zweite Oberfläche am Zylinder eine geneigte Ebene ist, die mit der ersten geneigten Ebene zusammenpaßt, wobei die Passung der geneigten Ebenen verhindert, daß sich die flexible Sperrklinke nach innen bewegt, und die Sperrklinke in einem Schlitz (26) im Zylinder hält.

### Revendications

- Seringue ayant un corps adapté pour maintenir un réservoir contenant du liquide à administrer comprenant une tige de piston (5) ayant des filets situés à l'intérieur du corps, un bouton de dosage (15) situé à l'extrémité proximale d'une telle seringue et un écrou interne (10) accouplé au bouton de dosage et fixé par vissage à la tige de piston utilisée pour régler la dose de liquide à administrer, et un moyen à cliquet (25) sur l'écrou (10) qui coopère avec un moyen à rochet (26) à l'intérieur du corps, caractérisée en ce le déplacement de l'écrou vers l'extrémité distale de la tige de piston à la fin de l'administration de la dose de liquide est empêchée par ledit moyen à cliquet (25) sur l'écrou en coopération avec ledit moyen à rochet (26) à l'intérieur du corps et dans laquelle se trouve un moyen sur l'écrou (28) qui coopère avec un moyen sur le corps (29) pour forcer le moyen à cliquet dans le moyen à rochet uniquement à la fin de la dose afin d'interdire la rotation de l'écrou dans le sens opposé au sens dans lequel l'écrou tourne lors du réglage de la dose de liquide à administrer.
- 2. Seringue selon la revendication 1 caractérisée en outre en ce que le moyen à cliquet sur l'écrou est un cliquet sur l'extrémité de l'écrou qui coopère avec des rainures sur l'intérieur du corps de seringue pour permettre à l'écrou de déplacer vers le haut la tige de piston filetée vers l'extrémité proximale de la seringue lors du réglage de la dose de liquide à administrer et en ce que les moyens sur l'écrou qui coopèrent avec les moyens sur le corps sont respectivement une première surface à l'extrémité de l'écrou et une deuxième surface sur le corps.

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3. Seringue selon la revendication 2 caractérisée en outre en ce que le cliquet est monté sur un bras flexible (32), la première surface à l'extrémité de l'écrou est un plan incliné et la deuxième surface sur le corps est un plan incliné s'accouplant avec le premier plan incliné dans laquelle l'accouplement des plans inclinés empêche le bras de cliquet flexible de se déplacer vers l'intérieur et maintient le cliquet dans une rainure (26) dans le corps.





